

EWG M2 Recommendation to the ICH Steering Committee
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
Format - Recommendation 5.2 16JUL1997

Title: SGML DTD Electronic Format for the Exchange of Individual Case Safety Reports (E2B Message)

Date: 16 July 1997

Background:

It is recognized that there is a need to exchange regulatory information with predefined structure in a common interchange format. M2 Expert Working Group was assigned the responsibility for facilitating the electronic transfer of Individual Case Safety Reports (E2B Message).

To facilitate the definition of structured information, Standard Generalized Markup Language (SGML, ISO 8879) Document Type Definition (DTD) can be used to define the structured data interchange format.

Recommendation:

The M2 Expert Working Group recommends the use of the ICH approved E2B/M2 SGML DTD as a formal definition of the electronic message for exchange of the Individual Case Safety Reports (E2B Message).

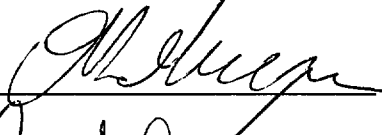
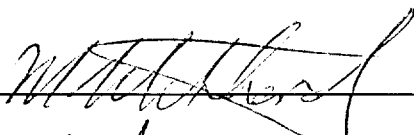
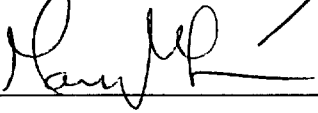
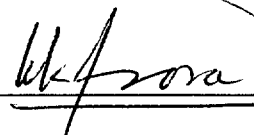

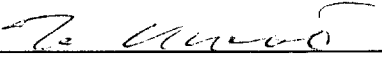
Conditions:

To enable EDI transactions, the ICH M2 Recommendation 5.3, EDI Header Specification for the E2B Message, must be followed.

Remarks:

- The first implementable version of the E2B/M2 SGML DTD will reflect the Step 4 document as approved by the E2B EWG;
- The SGML DTD will be updated to reflect the revisions made by the E2B EWG in the future.

Signatures:

<EU> 	<EFPIA> 
<FDA> 	<PhRMA> 
<MHW> 	<JPMA> 
<HPB> _____	(did not attend meeting)